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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,592	08/13/2001	Jess Paul Fuller	V0005/7097	9457

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EXAMINER	
NAFF, DAVID M	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 08/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,592	FULLER ET AL.	
	Examiner	Art Unit	
	David M. Naff	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,35,37-39,41,43 and 162-170* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-27, 35, 37-39, 41, 43 and 162-170* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 5/24/04 amended claims 5, 7, 9, 15, 24, 37 and 38, canceled claim 34 (28-33, 36, 40, 42 and 44-161 previously canceled), and added new claims 162-170.

Claims examined on the merits are 1-27, 35, 37-39, 41, 43 and 162-170, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-27, 35, 37-39, 41, 43 and 162-170 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuller et al (5,998,185) or WO 94/16058 in view of Williams et al (6,245,537 B1) and Mikos et al (5,514,378) and Fuller (WO 97/08291) for reasons in the previous office action of 1/30/04 and for reasons herein.

The claims are drawn to producing a silicone rubber article having a structure adapted for growth of cells or living tissue by mixing a sacrificial filler with a silicone rubber precursor, curing the resultant mixture at a temperature below 180^{0}C and removing the sacrificial filler to form a porous silicone rubber.

Fuller et al ('185) disclose producing a silicone rubber support structure for cells that is porous such as by being a sponge or foam (col 1, lines 35-66). The porosity may be controlled by including an additive during formation of the silicone rubber structure (col 6, lines 33-35). Metal powders may be added to provide a dense structure

(col 1, lines 53-55 and col 6, lines 45-46). Substances may be added to give the structure particular surface properties such as by providing agents on the surface that facilitate retention of cells (col 3, lines 35-40). Fuller et al (WO) contains the same disclosure as Fuller et al ('185).

Williams et al disclose producing a porous polymeric material for tissue engineering (paragraph bridging cols 22 and 23). Pores can be introduced into the polymeric material such as by using foaming agents, processing of fibers into woven or non-woven structures, phase separation and leaching (col 23, lines 6-22). Leaching involves dispersing solid particles such as a salt within the polymer and dissolving the particles out of the polymer with a solvent that does not dissolve the polymer. The particles may be dispersed in a solution of the polymer followed by evaporating solvent, and dissolving the particles (col 14, lines 10-26). Alternatively, the polymer may be blended with the particles, melt processed into an appropriate mold, and the particles leached from the polymer (col 14, lines 28-31).

Mikos et al disclose producing a porous three-dimensional matrix as a cell support for transplantation and implantation of cells (col 1, lines 5-10 and col 2, line 65 to col 3, line 4). Pores are formed using the particulate-leaching technique (col 3, lines 6-25 and col 4, line 55 to col 7, line 43) of adding particles such as salt particles to a solution of the polymer, evaporating solvent to form the matrix

and dissolving the particles out of the matrix by immersing the matrix in water.

Fuller discloses (page 3, line 11 to page 4, line 20) providing a textured (col 3, line 19) growth surface for cells by coating the inside surface of a growth bottle with silicone rubber, adding salt particles to the silicone rubber coating while still liquid, polymerizing the coating to form a solid layer studded (page 3, line 13) with the salt particles, and removing the salt particles by dissolution in water to leave a surface porous layer (page 4, lines 15-16) exhibiting a cratered or micro-cupellated structure.

When using a porous silicone rubber support structure for cells as disclosed by Fuller et al ('185) or (WO), it would have been obvious to form the porous support structure by adding filler particles to a silicone rubber precursor, curing and removing the filler particles as suggested by Williams et al disclosing leaching added solid particles as an alternative to using foaming agents (col 23, lines 7-15) and Mikos et al disclosing using the particulate-leaching technique to produce a porous polymer matrix for use as a cell support and Fuller disclosing using this type of technique to provide a silicone rubber coating with a textured surface that is surface porous and adheres cells. The disclosure by Fuller et al of controlling porosity by including an additive during formation of the silicone rubber structure (col 6, lines 33-35) would have suggested that adding solid particles and leaching will be an acceptable way of

forming silicone rubber containing pores. Fuller (page 8, line 26) would have suggested curing at below 180°C by disclosing curing at 70°C. No unexpected result is seen in using the particulate-leaching technique of the secondary references to form the porous silicone rubber cell support structure of Fuller et al. The conditions of the dependent claims are disclosed by the references or would have been obvious from the conditions disclosed. The silicone rubber of Fuller et al can be cured at room temperature as in claim 2 and is non-toxic as in claim 3. The secondary references disclose salts as in claims 11-14, 16 and 17, and removing the salts by dissolution as in claim 15. The salts of the references will not interact as in claim 4. Selecting specific forms of the salt such as granular, crystalline or amorphous as in claims 5 and 6 would have been a matter of obvious choice. Grinding or milling the filler as in claims 7, 8 and 13 would have been obvious to obtain a preferred optimum size as in claim 9 which is suggested by the size of fillers used by the secondary references. Wet-milling as in claims 8 and 14 is a well known procedure for obtaining a preferred particle size. Fuller et al suggest agents on the surface that facilitate retention of cells, and Williams et al suggest providing functional -OH groups as in claim 18 (col 8, line 45) and bombardment with electrons as in claim 19 (col 8, lines 25-47). The additive of claims 20-24 is suggested by Fuller et al adding density control agents such as metal powder. Fuller discloses producing a textured surface as in claims 25-27. The pores of the structure Fuller et al provide cell attachment sites as in

claim 35 and the structure of Fuller et al can be shaped as in claim 37. The pore size of claim 38 would have been obvious from pore sizes disclosed by the references. Fuller et al suggest a shaped structure having a desired size, and cutting as in claim 39 would have been an obvious way to obtain a desired shape or size. Combining the teachings of the references as set forth above would have inherently resulted in a silicone rubber and device or apparatus as required by claims 41 and 43. The conditions 162-170 would have been matters of individual preference and optimization within the skill of the art in view of the disclosures of the references.

Response to Arguments

It is granted as urged by applicants that the Fuller et al primary references are not using a sacrificial filler material. However, this is the reason that the secondary references are applied, and these references disclose the use of a filler that is removed to form pores. Using this method of pore formation as an alternative to using a gas would have been obvious to one of ordinary skill in the art. It is apparent from the secondary references that adding a filler, polymerizing and removing the filler is quite conventional in obtaining a porous polymer. Contrary to applicants' argument, the Fuller et al references are not directed only to producing coatings on roller bottles. The '185 patent discloses (col 2, lines 52-55) structure that can be granular, sheet, bead, tube, chip, strand, pad or block form. These structures are not a coating on a roller bottle.

While Fuller (WO) relates to a coating on a roller bottle, it is clear when Williams et al and Mikos et al are considered, the use of a filler to form pores is not limited to a roller bottle coating. The references must be considered together as a whole rather each alone. Additionally, the structure produced by the present claims can be a coating on a roller bottle. A coating is three-dimensional since a coating has width, even through it may be thin. While Williams et al and Mikos et al use a polymer other than silicone rubber, it would have been expected the particulate-leaching technique can be applied to silicone rubber in view of Fuller (WO) applying this type of technique to silicone rubber to form pores.

Double Patenting

Claims 1-27, 35, 37-39, 41, 43 and 162-170 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 5,998,185 in view of Williams et al and Mikos et al and Fuller.

It would have been obvious to produce the silicone rubber support structure of the claims of the patent using the particulate-leaching technique taught by Williams et al, Mikos et al and Fuller since this technique is a well known for producing porous polymers, and claim 24 of the patent requires controlling porosity by including an additive during formation of the structure.

Response to Arguments

Applicants rely on arguments traversing the 103 rejection to also traverse this rejection. As set forth above, these arguments are unpersuasive.

Conclusion

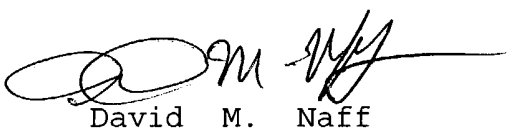
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff
Primary Examiner
Art Unit 1651

DMN
8/9/04